HP 05-1

July 17, 2005

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Office of the Secretary Consumer Product Safety Commission Washington D.C. 20207

PETITION: Boston Billow Nursing Pillow.

Reference: 16 C.F.R. Part 1500, # 1500.18(a)(16)(i)(A) through (E) and 15 U.S.C. # 1261 (q)(1)(A).

- Facts to support our claim for a modification of the regulations is enclosed in Appendix A.
- Request: We request that criteria # 5 of the Federal Regulations referred to above be amended to read: An exception is made when the product is specifically designed, intended and promoted for mothers to use when breastfeeding and requested by a Pediatrician or a Board Certified Lactation Consultant.

Please note that the CPSC already has approved an exception to these regulations by permitting the use of the Boston Billow nursing pillow with the wipeable cover if the sales are limited to hospitals and for use only in hospital settings. (CPSC letter of February 27, 2004.)

• Recommendations:

Recommendations are enclosed in Appendix B.

The Boston Billow Nursing Pillow has received overwhelming support from the medical community. They clearly need this product to help new mothers with problems to breastfeed. They instruct new mothers in the uses of the product and there are no suitable substitutes. We respectfully request that the Commission grants our request for an amendment as specified.

Sincerely

S. Erik Skoug President.

#### APPENDIX A.

Facts: We have carefully examined all the background material from the CPSC staff that was presented to the Commission in 1992 and which was the basis for the ruling by the Commission in 16 C.F.R. # 1500.18(a)(16)(i), (A) through (E), with reference to the 15 U.S.C. # 1261 (q)(1)(A).

The issue was clearly prone sleeping by infants on soft bedding that could adjust to an infant's face thereby causing potential suffocation and other hazards.

The recommendations were supported by a reference to reported incidents that, according to the CPSC Office of Economic Analysis, represented an **estimated potential** of **a single** infant's death on **100.000** units sold of the infant cushion that was banned in 1991. The CPSC obviously viewed this as an "unreasonable risk." The staff recommendations were supported by a medical study where the CPSC was a participant!

The CPSC legal staff has decided that the wording of the Federal Regulations referred to above also applies to the Boston Billow nursing pillow. We believe this decision is more agenda driven than based on a correct interpretation of the English language used in the Federal Regulations.

That be what is may. The fact is that the CPSC expanded its interpretation of the regulations to also include a product with no reported accidents or other negative aspects but that, to the contrary, has been recommended and requested by the medical community.

We have no problem with the continued ban of the infant cushion filled with granular material, "including but not limited to polystyrene beads or pellets." However, we feel it is wrong to include a demonstratively very useful product like the Boston Billow nursing pillow. This is a product that not only is a pillow with therapeutic properties for new mothers who have problems breastfeeding their babies, but that also have a direct positive effect on the new infants by making it possible for them to effectively obtain mother's milk.

Since this product has been thoroughly analyzed and approved by a large number of hospitals, and requested by Board Certified specialists on breastfeeding (RN, IBCLC) we request that these Federal Regulations be amended to so that this useful product can indeed be made available to new mothers who have problems breastfeeding. In our meeting with the CPSC Recall Staff on 2.13.2004, the CPSC staff stated that our nursing pillow was not needed because "there are other ways of feeding a baby."

This is a view that has been vigorously attacked by the American Pediatric Association and numerous others medical and other organizations that know of the unquestionable benefits of mother's milk versus artificial supplements.

Today, breastfeeding starts within hours after birth, when the mother is still in the hospital. If she has problems, and perhaps as many as one in ten new mothers have, the Lactation Consultant may recommend the use of a Boston Billow nursing pillow. The Lactation Consultant will instruct the new mother in the use of the Billow. Included in these instructions are warnings against leaving the baby on the pillow to sleep. Quite another point is the fact that the Boston Billow nursing pillow in its dimensions, construction and density makes it impossible for a baby to sleep on. It would roll off.

We suggest that the CPSC before making decisions should weigh risks versus benefits.

The risk involved, in an infant cushion, a product designed for infants to sleep on – alone – has been estimated at one possible death in 100.000 units sold. This, for a product that is quite different from the Boston Billow nursing pillow in construction and use.

Benefits: Based on hospital analysis, the Boston Billow nursing pillow is recommended by the medical personnel for use by about one in eight women giving births at a hospitals that use our pillow. We know from reports by the Board Certified Lactation Consultants that without the Boston Billow nursing pillow, these mothers would have had great problems providing their infants with nourishment.

(It should be noted that the U.S. and State government agencies have provided the Boston Billow nursing pillow, free of charge, to minorities that have up to three times the infant death risks over other groups.)

As you will see from the numerous letters of support we have received from the medical community, the Lactation Consultants are outraged that the ban been extended to include the Boston Billow nursing pillow.

Facts to support our claim for a modification of the regulations.

Medical.

Since 16 C.F.R. Part 1500, # 1500.18(a)(16)(I),(A) through (E) and 15 U.S.C. # 1261 (q)(1)(A) was implemented in 1992, medical research has advanced considerably. We suggest that if today's medical knowledge about causes for infant's deaths had been known in 1992, it is highly unlikely that these Federal Regulations would have been issued with current wording.

Medical research has established, beyond reasonable doubt, that the rebreathing theory referred to and discussed over five of the eleven page memorandum from Marilyn L. Wind, Ph.D. to the Commission is **NOT** the likely cause for the infant deaths referred to by Dr. Wind as a supporting basis for the ban.

The Journal of Pediatrics of April 2001 carried a study by Drs. Guntheroth and Spiers.

In their summary they state that: "their results did not support the rebreathing suffocation hypothesis. Deaths attributed to rebreathing could more logically be attributed to thermal stress.

The American Physiological Society Journal of January 3, 2002 has a peer reviewed report: "New Research Findings offers possible clues for avoiding Sudden Infant Death Syndrome." The study states:

"The rebreathing theory has been criticized because although increased CO2 is biologically significant, this condition is unlikely to cause nonspecific reversible depression of neuronal excitability or rapid death."

The study concludes that: "Hypoxemia, rather than hypocarbia, may be the more important factor when death occurs in infants sleeping with their faces covered by soft, porous bedding."

Furthermore, the study states: "Preliminary data revealed that there are often air channels around the infant's face, while sleeping facedown, which allow gas exchange with the environment and that they are hidden, since direct inspection does not suggest their presence."

When we presented the Boston Billow nursing pillow to the CPSC staff on 2.13.2004, we were not aware of this study. However, we made exactly this point in our presentation, that since the Boston Billow was narrow in shape and filled with beads there would be numerous air channels around an infants face even in the unlikely situation that a baby would rest facedown on the pillow and not roll off as would probably be the case.

Numerous medical studies are focused on sleep-related breathing disorders in infants. Central and obstructive hypoventilation are two of the pathological abnormalities that influences an infant's breathing. "These conditions can result in significant morbidity and/or mortality." (Stephen H. Sheldon, DO. FAAP. Professor of Pediatrics, Northwestern University Medical School.)

Pediatric Research of August 2004 brings up additional significant findings:

"Rare gene variations that change the function of proteins in babies who died suddenly may account for as many as 15 percent of infant deaths."

There are numerous additional medical research reports that cover various other reasons for the sudden death of infants. Not a single study support the rebreathing theory!

It is evident that there is no basis to uphold this ban on medical grounds.

Marilyn L. Wind, Ph.D., in her Memorandum to the Commission, refers to 35 infant suffocation deaths having occurred on one of the 950.000 infant cushions sold. Possible factors referred to were:

## Risk of Injury or Death.

"Risk of respiratory obstruction from the presence of pillows on which infants sleep."

Comment: The Boston Billow Nursing Pillow has a shape and consistency that makes it impossible for an infant to sleep on. The infant would fall off. We also refer to the study in the American Physiological Society Journal referred to above.

2) "Fabric wet from saliva further increasing breathing resistence."

Comment: The Boston Billow Nursing Pillow is used by the mother for breast feeding purposes ONLY. The Boston Billow Nursing Pillow is used by the mother to position her infant to ease breastfeeding. No saliva accumulation would occur without the mother being aware of it.

Fabric wet from saliva is more likely to occur on whatever other quilts/blankets/pillows/cushions/bedcovers etc.etc. on which a baby is placed.

3) "The inability of as many as 30-50 % of infants three months of age or younger to breathe through their mouths if their nasal passages are obstructed."

Comment: Statement of fact. No comment.

"an increase in the infant's need for oxygen (stimulating rapid breathing) when he/she is overheated due to excessive clothing or bedding. (decreased evaporative cooling occurs when a prone infant's face is burried in comprehensible bedding.)"

**Comment:** Yes, but this has nothing to do with the use of the Boston Billow Nursing Pillow.

5) "trapping of exhaled carbon dioxide around the infant's face when the infant's face is in soft, comprehensible bedding, resulting in rebreathing of air high in carbon dioxide and low in oxygen content."

Comment: In view of recent medical research, this statement is incorrect.

Specifically see The Journal of Pediatrics of April 2001 referred to above.

# Economic Analysis of Ban.

Dr. Wind refers to an analysis of the CPSC Directorate for Economic Analysis (EC).

"Based on **the observed risk** of about 10.5 fatalities per million products in use and a peak yearly production level of 250,000 infant cushions, EC **estimates** that the total annual benefit of a ban on infant cushions is the avoidance of two to three infant deaths per year."

We have conferred with Professor Marvin Freedman, professor of Mathematics and Statistics at Boston University.

"No statistical conclusion can be drawn from the sample referred to."

The conclusion by the Directorate for Economic referred to above is both wrong and systematically inaccurate. It is, as they say, an estimate based on "we think" reasoning.

The "observed risk" for the Boston Billow has also been established:

Facts: Over 8000 Boston Billow nursing pillows have been used by breastfeeding mothers all over the United States over the last 5 years without a single reported injury.

**Facts:** For over 25 years, hundreds of thousands of the identical product has been used by breastfeeding mothers in Scandinavia, Germany and other European countries, without a single reported injury.

Facts: Risks: The Boston Billow nursing pillow has been specifically evaluated and approved by 27 hospitals. Furthermore, the Boston Billow is used in over 70 hospitals with over 75.000 annual births. This approval by pediatricians, lactation consultants and risk analysis managers includes the premier hospitals in the United States. Clearly, these hospitals concluded that there was <u>no risk</u> in using the Boston Billow nursing pillow.

Congress has charged the CPSC "to protect the public against unreasonable risk of injury associated with consumer products." In the case of the "infant cushion" for a baby to sleep on, "unreasonable risk" is equated with "observed risk" and "estimated" as one potential death per 100,000 products sold!

In the case of the Boston Billow nursing pillow unreasonable risk is equated with nothing but a potential risk "if a breastfeeding mother who uses your nursing pillow falls asleep immediately after breastfeeding, the infant is at risk of suffocation." (CPSC Letter of 7.13. 2004.) –Duh !!!!

The Directorate for Economic Analysis states:" The potential loss in consumer utility should largely be offset by the availability of close substitutes in the same price range."

With respect to the Boston Billow Nursing Pillow, no close substitute is available.

Facts: Numerous letters of support by medical professionals refer to the fact that there are **no close substitutes available** that performs the same function as the Boston Billow nursing pillow. See Appendix B.

Facts: A survey of several hundred Board Certified Registered Nurses and Lactation Consultants (RN, IBCLC) – medical professional with breastfeeding as a specialty - rated the Boston Billow nursing pillow at 9.2 out of a maximum 10 for "best".

There is an additional important aspect of the Boston Billow Nursing Pillow that must be taken into consideration. The availability of this product to mothers with breastfeeding problems, or who nurse seriously premature of ill infants actually save lives. The Boston Billow is the only nursing pillow used by hospitals all over the country in their NICUs — Newborn Infant Care Units - where the smallest and sickest infants are taken care of.

Mothers come in as soon as it is feasible to start breastfeeding their infants, using the Boston Billow with the wipeable cover.

Once they go home, they are deprived of this product and there are no substitutes. Reports from lactation consultants indicated that often the mothers stop breastfeeding with potentially dire results for both infant and mother.

It is therefore immoral to prevent this product from reaching mothers and infants who desperately need it, and where Lactation Consultants have recommended the pillow and illustrated it's use.

#### Pros and Cons.

#### Pros.

- The Boston Billow nursingpillow is requested and endorsed by the medical community.
- The Boston Billow has been reviewed and approved for use by medical and risk staff in 27 hospitals. The Boston Billow is used in more than 70 hospitals.
- The Boston Billow nursing pillow is demanded by mothers to ease breastfeeding.
- The Boston Billow nursing pillow is the only pillow suitable for use when mothers breastfeed premature infants.
- The Boston Billow nursing pillow has been endorsed by public agencies around the country to encourage breastfeeding by minorities, primarily African-Americans and native Americans.
- There have been no reported incidents in connection with the Boston Billow after more than 5 years of use in the United States and over 25 years of use in Europe.

# Cons. (CPSC Staff comments. 2.13.2004.)

- The Boston Billow can be easily flattened. (Demonstrated by the staff with karate chops.)
- A Boston Billow could be given as a gift to moms who had not received instructions in its use.
- The Billow could be sold or donated by someone after use and could end up in a flea market where another mother could buy it and use with her baby.
- A grandmother, or a baby sitter, could place the baby in a crib and support it with the pillow.
- There are other ways to feed a baby than breastfeeding!

#### Options.

- The infant cushion that was banned in 1992 was a product specifically
  designed and promoted for infants to sleep on.
  Out of about one million units sold, about 30 reports were received by the
  CPSC of infants deaths possibly attributed to use of the infant cushions.
- The Boston Billow nursing pillow is a product specifically designed and promoted to aid mothers when breastfeeding. In design and promotion it is completely different from the infant cushion of 1991.

That the Lactation Consultants consider the Boston Billow nursing pillow an important product to help breastfeeding mothers is clearly expressed in the numerous letters of support we have received expressing outrage at the CPSC decision.

It seems peculiar that the CPSC staff, with no understanding of or experience in, the problems involved with breastfeeding, make medical decisions that are contrary to the opinions and experiences of the medical community.

Based on the facts of this case, we request the Commission to amend the Federal Regulations in question to read:

"An exception is made when the product is specifically designed, intended and promoted for mothers to use when breastfeeding and requested by a pediatrician or a Board Certified Lactation Consultant."

## Appendix B.

In Appendix A we have laid out the risk factors and the medical realities in support of an amendment to the Federal Regulations, as requested.

When zero risk has been established, or can conceivably be pinpointed using common sense, the utility of a product must be weighed against the perceived risk. There is no way that one can uphold a view that the Boston Billow nursing pillow represents and "unreasonable risk" to an infant and more than any other pillow or whatnot around the house represents a risk.

We suggest that it is also the task of the CPSC in considering whether to allow a product to be marketed – or not – to evaluate the utility of a product. The utility is how useful a product is to consumers. When it comes to the Boston Billow nursing pillow, the medical profession clearly states that this pillow is unique in the way it can assist mothers when breastfeeding in general and specifically. when breastfeeding premature or critically ill infants. There is no substitute and the ban of the Boston Billow nursing pillow directly contributes to the endangerment of infants. That is the aspect of "utility" that the medical community considers – not the economic aspect of the ban but the added risk to babies that the ban causes.

As you will see from the enclosed letters of support from Lactation Consultants, there is incredulity in the fact that the CPSC could issue a ban on such a useful and critically important product. The medical profession unanimously support our request for an amendment to the regulations!

We also want to point out the curious fact that the CPSC staff singled out the Boston Billow nursing pillow for a ban and not other nursing pillows that clearly represent a larger risk to infants. Products that are **NOT** universally recommended by medical professionals and products that are **NOT** used in hospitals.

In the Executive Summary to the Commission, dated May 14, 1992, # 2 B, points (1) to (5) the staff refers to rebreathing problems for infants, face down on the infant cushion as reason for the reported deaths and banning of bead filled infant cushions.

In support of their argument, the staff refers to "recent studies" by Drs. Thach and Kemp and their conclusion that "the softness and malleability of infant cushions are likely factors in the apparent suffocation deaths of infants." Furthermore that the tests were based on an infant beanbag cushion, an infant comforter, and an infant blanket.

However, in a deposition under oath of Drs. Thach and Kemp, taken by David E. Bernsen, Esq. of Benckenstein, Norvell, Bernsen & Nathan Esq. and reported to Ms. Sadye Dunn of the Office of the Secretary, CPSC, on 10. 7, 1991, Dr. Kemp admits that Drs. Thatch and Kemp ALSO tested a cushion filled with foam. According to Dr. Kemp, the results of blood gas studies using the foam filled cushion were identical to the polystyrene bead filled cushions. Their study indicated that a polystyrene filled cushion was in fact no different from other cushions that were on the market. (Deposition pages 80-81.)

The staff had this information in hand for 7 months before they prepared their briefing package of May 14, 1992 to the Commission. We find it peculiar that the staff recommendation singled out granular fillings when they were fully aware of the fact that foam filled cushions produced the identical results in the Drs. Kemp and Thach study.

The staff neglected in its recommendations to the Commission that all infant cushions used for infant support (!) and breastfeeding should be banned "because of their softness and ability to conform to an infant's face, present an unreasonable risk of injury", as foam filled infant cushions represented the identical risk.

### Boston Billows.

# Appendix B. Page -3-

- Foam filled cushions also have a flexible covering
- They are filled with foam that according to Drs. Kemp and Thach represents the same re-breathing danger as cushions that are loosely filled with beads and/or pellets.
- · They are easily flattened
- They are able to conform to the body or face of an infant
- They are intended AND promoted for use by children under one year of age.

With reference to 16 CFR Ch. II § 105.9 the Commission should have banned these infant cushions since foam filled infant cushions also represents an "unreasonable risk of injury and it is reasonably necessary to eliminate or reduce the risk of injury" from this type of products.

If the CPSC is consistent in its evaluation of products in the market place it should evaluate all products used when mothers breastfeed to ascertain that really dangerous products are taken off the market.

#### **Enclosed:**

Letters from the medical community in support of the Boston Billow nursing pillow.

3.11.04.

Hi Erik!

I am attaching the letter that I sent today. As you know, in the terms of my contact with Healthy Children I cannot endorse any products....so please do not share it with anyone,,,it is for you only (and of course the government).

I hope that this ends for you soon...

I can't imagine why a little tag or educational material can't be included as there have been no incidents.

Good Luck! Karin

Allem Schoem, Director Recalls and Compliance Division Office of Compliance US Consumer Product Safety Commission 4330 East Highway West Bethesda, MA 20814 March 11, 2004



## Healthy Children

a non-profit research and educational institution

Karin Cadwell, PhD, RN. IBCLC
Consulting and Training

8 Jan Sebastian Way, Ste. 13 • Sandwich, MA 02563-2359 **Phone:** (508) 888-6044 **Fak:** (508) 888-8050

#### Good Morning:

I am writing today about the breastfeeding aid, the Boston Billow. We use it exclusively to aid mothers in positioning the baby at the breast because it is the only product that can be individually shaped to accommodate the mother's anatomy and the baby's ability. For example, with a grant from the March of Dimes, we studied the issue of establishing breastfeeding in the community after babies had been born prematurely and had spent weeks or months in the hospital. These babies have poor muscle tone so are often unable to hold their heads in the appropriate position. Also, they lack subcutaneous layers of fat and that includes the fatty pads that term babies have in their cheeks. This means that they cannot hold the nipple in the mouth by themselves; the mother has to use her hands to keep the baby in position. We found that only the Boston Billow was able to aid the mother because it maintained the desired and appropriate position. We were able to assist all of the mothers to breastfeed and the babies will have the advantages of getting their own mothers' milk.

I understand that you, and your colleagues, have concerns about what other uses the mother or other caregiver may have for the pillow after she has used it for breastfeeding. Certainly there are many "innocent" items in the home including stuffed animals, pails, pillows and recliners that have proved lethal to babies and toddlers. I hope that you will find a way, perhaps by attaching a "billow" use tag to the product that will protect the consumer and allow us to continue to use this unique and irreplaceable product.

Thank you for your attention to my concern.

Karin Cadwell PhD, RN, FAAN, IBCLC



Date: From: To:	Thu, 9 Sep 2004 09:18:58 -0700 "Minnick, Jessica (Tacoma)" < Jessica Minnick@fhshealth.org > contact@bostonbillows.com

To whom it may concern,

We are with the Franciscan Health System in Washington State. We were shocked, to say the least, when we heard of the recall for Boston Billows. We were one of the first West Coast Hospitals to start using the Billow. It is actually the only breast feeding pillow we recommend or sell to our mothers That is what it is designed for and used as, a aide in helping mothers nurse their babies.

It would stand to reason that a competitor would lodge such a complaint, especially when it had a corner on the market. The Billow is a superior nursing pillow and it probably is out selling the competitor.

We believe if you reevaluate this decision and actually see and use the Billow, you will see that the complaint is baseless and really does not pertain to this Nursing Aide.

Thank you for your time and consideration in this matter.



# Healthy Children

a non-profit research and educational institution

Allem Schoem, Director Recalls and Compliance Division Office of Compliance US Consumer Product Safety Commission 4330 East Highway West Bethesda, MA 20814

March 11, 2004

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Thank you for your attention to my concern.

Karin Cadwell

Karin Cadwell PhD, RN, FAAN, IBCLC

Phone: (508) 388-8044 • Fax: (508) 888-8050 • E-Mail: info@healthychildren.cc • Web: www.healthychildren.cc



August 12, 2004

Mr. Eric Skagg Boston Billows, Inc. 28 Charron Avenue Nashua, NH 03060

Dear Eric:

This letter is to express again my unreserved support of your product, the therapeutic BillowPillow.

This product has been invaluable in my practice as the Outpatient Lactation Consultant for my employer, Chesapeake General Hospital. I frequently have mothers coming in for consulations for breastfeeding problems, who already own other pillow-like products to assist them in positioning their babies. Many of these mothers have been unable to get their babies well-latched, which is essential for effective milk transfer. These problems are sometimes caused by the pillows they have been using, which are generally too stiff, too big, or too tall, to enable effective positioning. This is especially true if the baby is small, premature, or compromised in some way.

I use your BillowPillow in all my consultations, and mothers are quick to realize how it truly is different. It enables and encourages good latching technique, even in awkward situations such as mothers with carpal tunnel syndrome. It's flexibility and versatility as compared to other "nursing" pillows is so much greater that many of these mothers purchase a BillowPillow despite already owning another product. I am sure that the Billow's use by mothers facilitates effective breastfeeding, thereby being a means to truly preventive health care, and to healthier babies and mothers as a result.

We have long needed "health" care, rather than the "sick" care we have today. Your BillowPillow is a positive factor in helping me provide such care. Thank you for a GREAT product. Keep up the good work!

Sincerely,

Kay McKee, BA, ICCE

**Outpatient Lactation Consultant** 

August 24, 2004

To Whom It May Concern:

We first trialed the Boston Billow Nursing Pillow nearly 4 years ago. We loved it and more importantly, our patients loved it. I have worked with nursing mothers and babies for more than 25 years, and have seen and tried many, many "nursing pillows" in my time. The Billow is my all time favorite.

Mothers do not use this pillow to put babies to sleep. It is used to support the baby during breastfeeding. It helps enormously in positioning a baby comfortably at breast. It fits women of ALL sizes and shapes, unlike most every other pillow out there. The unique design of the Billow allows it to sit comfortably around a woman who has recently had a cesarean birth.

It is wonderfully durable, and can be washed over and over. I know this because when the pillow first came out, we liked it so much; we used it in our outpatient practice office before the wipeable cover was available. I took it home and washed it every night.

I was very saddened to receive notice that this wonderful product has been recalled. It is truly the best nursing pillow available. I feel that the regulations written to protect baby's safety are of the utmost importance. There could not be a subject more near and dear to my heart. However, there has been a grave injustice done in this case. This pillow was never intended as a sleep aid. It is to be used to support and position a baby at breast while breastfeeding. I cannot see how suffocation could possibly be an issue. I do not see how this product could be deemed unsafe.

Please reconsider. You have no idea how many mothers and babies have benefited from the use of this product. Mothers love it. Lactation consultants love it. Babies thrive because of it.

Bonnie Calle Bonnie Cable RN, IBCLC Mt. Carmel Health System

**Outpatient Lactation** 

5965 E. Broad St., Suite 100B

Columbus, OH 43213

614-234-8130

bcable@mchs.com

Erik 
Sam so sorry

to hear about this.

Dwell help in any

way possible.

Way possible.

Thanks for fighting

this: Sure

Kay McKee, RN, IBCLC. Chesapeake General Hospital Chesapeake, VA.

I would like to give my unreserved endorsement of the Boston Billow nursing pillow. This pillow is different from the Boppy in many ways. The difference is probably best illustrated by the fact that many of the mothers who use my office Billow during outpatient lactation consult will purchase one on their way out, despite the fact that they already

The Billow is flexible, "mushable", enabling the mom to adjust it's thickness and firmness to best meet her needs in latching her baby well. Since effective latch is the critical foundation for effective milk transfer (and resulting supply for mom, gain for baby, and ultimate health of both), this difference should not be taken lightly. The Boston Billow is no more like the Boppy than are any of the many other pillows on the market such as the "My Best Friend" and others, and is by far the best pillow we have ever used.

Any court that would inhibit the availability of this product to mothers would be doing them a great disservice.

Please feel free to use our facility as a reference for your wonderful product.

Best wishes in fighting off the giants.



40

#Kershaw Jane" <Jane.Kershaw@HCAHealthcare.com>
To: "gaapaa@yahoo.com'" <gaapaa@yahoo.com>, "Sands Katie" <Anita.Sands@HCAhealthcare.com>
Subject: RE: The Boston Billow nursing pillow.

Date: Mon, 9 Feb 2004 14:29:21 -0600

I am the manager of the Lactation Service Department for Centennial Medical Center. We first began using the Billow Pillow in September of 2002. Previously we have used several other types of nursing pillows. Our patient satisfaction has been excellent with these pillows. We are a small center and we use about 5-6 a month of these pillows. The chief advantages of this pillow over Boppies and other pillows includes: they are moldable and can be adapted easily to various size mothers., they are comfortable on incisions (post C-section and other surgeries.) They can adapt to various lengths and sizes of babies from tiny problem to extra large babies. They can be used to accommodate various positions for breastfeeding, including football hold, clutch hold, cradle hold and even side-lying. Moms can use them behind their backs, if they need back support, just pulling the end out enough to support the baby such as in football hold. If you put them around moms sideways, the tail anchors behinds mom's back and prevents slippage - yet doesn't hurt mom's back. They are washable and don't bunch up after washing, nor do they flatten out with extended use. They are DESIGNED for breastfeeders, not being used as an aftermarket product. Our moms love these pillows. They are available with a washable cover which we use because these are so versatile. They are light and comfortable. Please keep up the fight to keep these pillows available.

Jane Kershaw, RN, BS, IBCLC Coordinator "A Mother's Place." Lactation Support Services Womens Hospital @ Centennial



Annette Leary, BSN, IBCLC, RLC Arnold Palmer Hospital Orlando, FL.

Il first came in contact with the Boston Billow pillow in 1999. As a lactation consultant, I found a pillow that was comfortable for all the mothers I worked with, no matter what their shape or size. They could easily conform the pillow to raise the baby to breast level and it wasn't too tight, especially around their waste nor did it create a "crater", as the parents often refer to it, (Many of them had a pillow from another distributor, the "Boppy" where the baby often falls into the area in front, across the mother's waist and slip away from the breast causing nipple damage as the baby slips off the breast.) Due to the movable filling inside the Boston Billows pillow, the mothers are able to keep the babies at breast level, by moving the filling around and bringing and keeping the babies at breast level. The other pillow often left them feeling frustrated, with altered body image ("I thought I was too fat to use my "Boppy" was a common comment) and

Many of the mother's find the Boston Billows pillow comfortable for themselves to use as a back rest or to sit on when they have a sore perineum from delivery. This of course while not breastfeeding the baby.

I work in an area that does about 1,000 deliveries a month and many of the mothers have other nursing pillows, when they use mine during a consult they are very pleased and usually purchase a Boston Billow. Our NICU lactation consultant also enjoys using on with her NICU moms and finds them helpful in positioning these fragile babies at breast level.

I am glad there is such a great product available to mothers and babies!

Sincerely, Annette Leary BSN,IBCLC,RLC



Date: Fri, 3 Sep 2004 09:00:35 -0400

From: "Pam Hirsch, RN, BSN, CLC" <pam.hirsch@ADVOCATEHEALTH.COM>

**Subject: Boston Billows** 

Hi, Anne: Like you I was shocked to hear that the company has recalled these pillows. I and my moms love them as it is so much easier to "schmush" them to conform to mom and her baby than some of the other pillows out there. But apparently the reason these pillows were recalled is a "possible" suffocation hazard if the baby is laid face down across the pillow. I would think using a little common sense would prevent problems. Why can't use of this pillow fall into the same caution category as use of standard bed pillows, rather than a total recall of what is otherwise a useful product. Does this mean all bed and other pillows should be recalled? I shudder to think what my quality of sleep would be like if there were no pillows available. BTW, I have no financial interest in this company.

Pam Hirsch, RN,BSN,CLC Clinical Lead, Lactation Services Advocate Good Shepherd Hospital Barrington, IL USA

### "Linda McGee" < Linda. McGee@bmhcc.org>

Date:

Tue, 24 Aug 2004

I am writing in support of the Boston Billow pillow. I have used it with clients for the last four to five years. No complaints or problems have been reported. Not all pillows are alike and repeatedly the clients choose the Billow Pillow. The proper support during nursing helps with success and decreases some potential problems.

Thank You, Linda McGee RNC, IBCLC

Baptist Memorial Hospital for Women 6225 Humphreys Bld.
Memphis, Tn 38120
901-227-9621
linda.mcgee@bmhcc.org

To Whom It May Concern: the Boston helen for more than I have been muit the Boston helen for more than breast that their bolin. Buttoned in hey to an effective latch at the livest is hey to an effective latch at all carly weeks. Pleas, make sure that This blushle bod is not land of the second it. Thunk you, Sorter Riller is the out musing piller I sue, because I think it is rafe and will adjust for mothers of different lyse and shaper; and shaper; Galf Hout, Trece E-mail: Wwopal Co act. con-Credentials: BA TRCLC Telephone number: (973)234-45Please write here:

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Bostan Billero can At a wiety of new moms some norsing pilows dure too small "He small "bends" inside make the much easier norsing because you can mad years now and our customers love tham. vie have add boston fallows for calaut 3 the pillow morehain some competitions

Name: KINCE FOUNDING Hospital or organization. VI

Please write here:

Han the Boppy, or any other pillow they have tried, Please help to get the newsy pillow back on the wastest. Dear Conspessman Bradley, advance for holping to want to thank you in advance for holping to want the regulation banning the use of the boston Billow Musing Pillow. My mothers long the pillow they find it much more cutified

Credentials: RN, 1BCCC Hospital or organization. パルトはいけん Name: (Seralding Dacis

Telephone number: フィュースパターピート

Dear Congression of Brailly, about the recall of the Boston Billows of an give districted about the recall of the Boston Billows which to have been using for my client for the mothers. We have safely used this product and its use is for the mothers upon with 15 Lyng on the mother's upon with 15 Lyng on the mother's upon we will not be used for which's and we estudiate our hospital christsand employees; waterskoof cover while In our hospital sething we wan a waterskoof cover while seeing our baby and mother chiests; 4/12/04 Invesely yours, Unxima C. Mose Ruke Credentials: 841 To purchase the HERApertic Billows Pillows. Name: VIRGINIA C MOORE Please write here:

Please write here:

The Baston Billow novering pillow has been the nutsing pillons we have used for years - it has sowed wowell any other pillay, I would think any mother would I I weally clove how It works with our habies, so ( ) to beave buby unattended ????

Credentials: RN IBCLC Hospital Hospital or organization. 【hospital or organization. 【hospital or organization. 【hospital organization. 【hospital or organization.] Name: Letesan Patterint

product. I urge you to reserve this decision this product. I am outraged that such Maternal + Infant Safety is ever hospitals number one concern. Our facility has Credentials BANRAC, I BCCC, Manuar a claim could be made against this successfully & Safely used the Boston breast feeding for six years. Mothers receive instruction on the utilization of Billow pillow to assist mothers with Hospital or organization. <u>Northside 中の向け</u>まして目的中のne number: 七〇七・3〇3~3966 Name: LOTA Alle A

E-mail: Deth. allend nothside.com

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Date: Tue, 10 Feb 2004 07:55:18 -0500

From: "Barbas, Kimberly" <Kimberly.Barbas@childrens.harvard.edu> 😤 Add to Address Book

Subject: Survey-

To: SES@bostonbillows.com

- What is your overall opinion of the Billowpillow? I like the Billow, and find it more comfortable to use than a firm Boppy Style pillow
- 2. Do you find the Billowpillow suitably firm for its purpose, or should it be filled with more or less filling? Itis suitably firm - would lead towards MORE filling, not less. Does not hold up over time in the hospital, becomes very flat....not sure how it wears in a private home.
- 3. Any comments about colors or patterns? My mothers like the Denim Blue, and the Bright, modern styles and colors, things that can be gender neutral sometimes sell well. Pastels are not in favor. Have you tried a red/white/black developmental pattern material?
- 4. We supply the Billowpillow with a wipeable cover for lactation consultants only, to be used for demonstration purposes, in NICUs etc.? Do you have them? Yes - love them - easy to clean, covers have held up very well. We usually put them in a pillow case when using the pillow.
- 5. Some mothers have asked that we offer the Billowpillow with a waterproof cover for the inner pillow, while keeping the outer 100 percent cotton cover. This would make it considerab

Ŋ

easier to keep the pillow clean. Do you think this is a good idea and would you

consider the pillow safe with the inner cover made of a waterproof material similar to what is used in hospital pillows? Yes - I would think being able to remove and wash the cover, with the waterproof underneath would be a selling point. I think it is safe...I can't think of any reason it wouldn't be..

Now, the Billowpillow comes with both the inner and outer covers made of 100 % cotton fabric.

Do you consider the current Billowpillow with the cotton covers a safe product? Yes - but would include a safety note cautioning against having the infant sleep on the billow, or leave the infant unsupervised on the pillow. (SIDS risk?) Bean Bag chairs were determined a safety risk years ago - I recently saw one, and the company removes the zipper pull once the bean bag is closed, so children cannot crawl inside...

- 7. Do you demonstrate to mothers how to use the Billowpillow? In hospital yes
- 9.. Do you recommend the Billowpillow to them? If mothers ask I suggest it, and often when they use one here, they want to buy one.
  - 10. Do you know our other products? The BreastBillow for mothers with large breasts and the small Port-A-Billow? If not, would you like to receive information? I use the breast Billow occasionally I am aware of the port-a billow, but have not used it, or seen it used or seen literature on it.
  - 11.Do you know our brochures? If so, what is your opinion of them? I helped with the Billow brochure! I like it! Have not sen any others.

Any other promotional materials or activities you would like to see? It might be nice to have sample material swatches for ordering colors

12.Any other comments or suggestions? Keep up the good work!

Kim Barbas, EN, IBLLC.

Thank you for your response. We really appreciate it.

S. Erik Skoug, President, Boston Billows, Inc.

(SES@bostonbillows.com)create

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MELROSE WAKEFIELD HOSPITAL. Page 10 LACTATION CONSULTANT.

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Date: Frl, 13 Feb 2004 15:38:21 EST

Subject: 🚰 feedback

To: SES@bestonbillows.com

Hi Erik,

Went to the Superbowl (!!!) and just finally getting around to e-mail etc. Wanted to give you my feedback on the Boston Billows.

- 1. My overall opinion: I love it.
- 2. Is it suitably firm?: Initially yes, it does seem to settle after awhile, though I haven't gotten any complaints.
- Colors and patterns: I like how you change the colors and patterns frequently, but I would like to see some kind of brochure for those ordering that would allow me to choose which patterns I would like.
- 4. Waterproof inner pillow?: Sure, why not?
- 5. Current product safe?: Yes
- 6. Demonstrate?: If I use the pillow with an in-patient, yes I do demonstrate. If I sell the pillow to an out-patient, no, I do not demonstrate.
- 7. Do I recommend the BillowPillow to moms?: This is a good question. As a health care provider I find the business end of my practice, especially the "selling" of products VERY DIFFICULT, as I believe many in our position do. Unlike a physician or most other health care providers who have secretaries and office managers, etc to deal with the business end of things, Lactation Consultants are in the awkward position of telling the patient they "need" something (pump, shells, pillows etc), then collecting the money for these items themselves. I encourage moms to use a pillow if I think it's necessary, and I let them know we carry pillows, but that is about as far as I'll go.
- 8. Other Products? Yes I do know about your other products. I would like more information on your Port-A-Billow.
- Brochure?: Nice
- Other promotional materials or activities?: I would be interested in hearing from others in similar situations (hospital LCs) and how they promote the Boston Billows.

11. Other Comments: As always it is a pleasure dealing with your company. Both you and Ken are always pleasant and easy to work with. I would like to improve our sales, but am not quite sure how to do it?

Hope this info is helpful, Sincerely, Mary Foley RN IBCLC Melrose-Wakefield Hospital Lactation Program Coordinator

#### Forwarded Message [ Save to my Yahoo! Briefcase | Download File ]

From: BreastfeedingABC@aol.com

Date: Mon, 9 Feb 2004 10:57:36 EST

Subject: (no subject)

To: BreastfeedingABC@aol.com

#### HTML Attachment [ Scan and Download | Scan and Save to my Yahoo! Briefcase ]

Dear Mary, Now, at the start of a new year, we contact our customers to get feedback about our Boston Billow nursing pillow, (the Billowpillow,) its quality and features as well as your view of our service and promotional materials. It is important that we hear from you so we can know where we stand and where we should focus our attention. Please therefore reply to the few questions listed below and return it to us. Thank you.

What is your overall opinion of the Billowpillow?

Do you find the Billowpillow suitably firm for its purpose?

Any comments about colors or patterns?

We supply the Billowpillow with a wipeable cover for lactation consultants only, to be used for demonstration purposes, in NiCUs etc.? Do you have them?

Some mothers have asked that we offer the Billowpillow with a waterproof cover for the inner pillow, while keeping the outer 100 percent cotton cover. This would make it considerably easier to keep the pillow clean. Do you think this is a good idea and would you consider the pillow safe with the inner cover made of a waterproof material similar to what is used in hospital pillows?

Now, the Billowpillow comes with both the inner and outer covers made of 100 % cotton fabric. Do you consider the current Billowpillow a safe product?

Do you demonstrate to mothers how to use the Billowpillow?

- 9.. Do you recommend the Billowpillow to them?
- 10. Do you know our other products? The BreastBillow for mothers with large breasts and the small Port-A-Billow? If not, would you like to receive information?

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From: "Michelle West" <mlchelle7218@msn.com> Add to Address Book

To: gaapaa@yahoo.com Subject: RE: The Billowpillow Date: Tue, 03 Feb 2004 10:39:41 -0800

>From: "S. Erik Skoug" < qaapaa@yahoo.com> >To: michelle7218@msn.com >Subject: The Billowpillow >Date: Sun, 1 Feb 2004 10:09:32 -0800 (PST)

>Hello,

> >

>Last year you purchased a Boston Billow nursing pillow. We hope that

>and your baby are doing well and that the "Billowpillow" was of assistance

>when breastfeeding.

>Now, at the start of a new year, we contact you to get customer feed back.

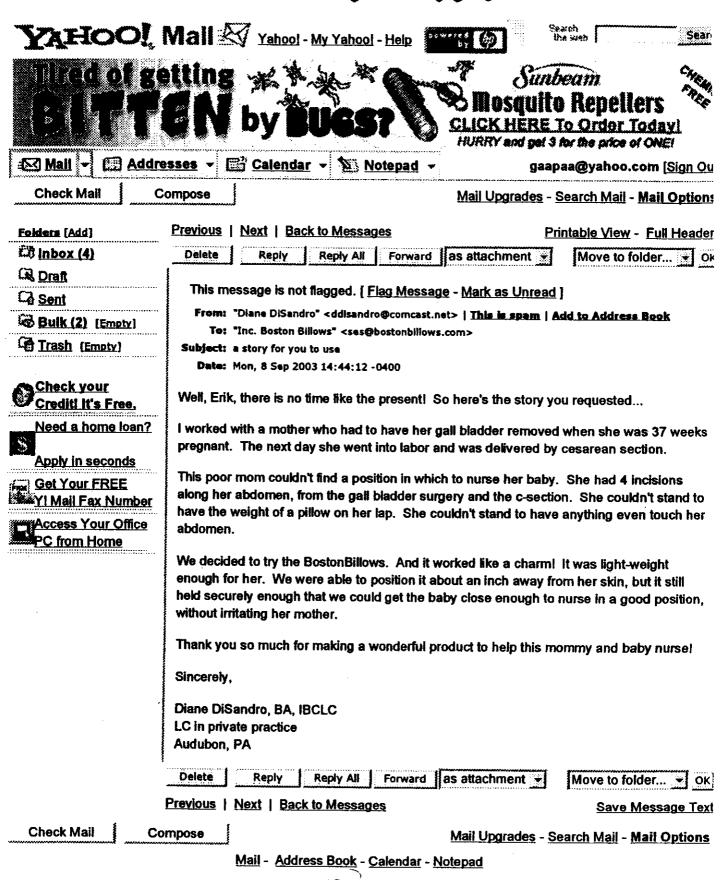
>It is very important to us that we hear from you. That is the only way

>can improve our products and operations.

What is your overall opinion of the Boston Billow nursing pillow? I

>bought the pillow for my daughter. I am an IBCLC and work on a >mother/baby unit of a hospital. I really like the pillow because it

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and it washes up nicely.
>"moldable"
>
>
       Any suggestions for changes or improvements? More colors,
>B.
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>c.
       Were you instructed in the use of the Billowpillow by a
lactation
>consultant?
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>D.
       Did the lactation consultant recommend the Billowpillow?
have
>recommended it to clients. We have a sample in our outpatient clinic.
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>性
          Did you ever put the baby down on the Billowpillow to sleep?
>
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>F.
             Did you try the Boppy when breastfeeding, and how did it
>for you?
           The Boppy is too stiff and only works for some women's body
            It seems to be the most well known however.
>builds.
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            Do you consider the Billowpillow a safe product? Yes.
>G
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>H.
           Will you, or did you, recommend the Billowpillow to others?
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           Any other comments or suggestions, including new products
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Date: Mon, 09 Feb 2004 10:47:23 -0600

From: "Ruth Sweet" <jsweet@ssc.wisc.edu> #Add to Address Book

Subject: Re: The Boston Billow nursing pillow To: "S. Erik Skoug" < gaapaa@yahoo.com>

! like your pillow best of the nursing pillows, however, I fit better in the less is better school and teach how to position with as few gadgets as possible. I only use pillows for mome with special needs or those who state that they need or prefer one. Then I always suggest the Billow Pillow. That said, I will now answer your questions:

- What is your overall opinion of the Billowpillow?
- Do you find the Billowpillow suitably firm for its purpose?

A little firmer would probably be better for most uses.

3. Any comments about colors or patterns?

I prefer bright (I mean gaudy) prints. My customers usually prefer denim colors.

4. We supply the Billowpillow with a wipeable cover for lactation consultants only, to be used for demonstration purposes, in NICUs etc.? Do you have them?

I have one.

5. Some mothers have asked that we offer the Billowpillow with a waterproof cover for the inner pillow, while keeping the outer 100 percent cotton cover. This would make it considerably easier to keep the pillow clean. Do you think this is a good idea and would you

consider the pillow safe with the inner cover made of a waterproof material similar to what is used in hospital pillows?

Fine to me

6. Now, the Billowpillow comes with both the inner and outer covers made of 100 % cotton fabric. Do you consider the current Billowpillow a safe product?

Yes

7. Do you demonstrate to mothers how to use the Billowpillow?

sometimes

9.. Do you recommend the Billowpillow to them?

sometimes

10. Do you know our other products? The BreastBillow for mothers with large breasts and the small Port-A-Billow? If not, would you like to receive information?

Women with large breasts do better if they allow the breast to be where it belongs and place the baby below. That is way nursing pillows are a really bad idea for women with large breasts.

I have not seen the Port-A-Billow. I might like it but would need to handle it before I would order any.

11. Have you seen our brochure? If so, what is your opinion of them?

Any other promotional materials or activities you would like to see?

I use your brochure when I have them but would prefer something a little lighter. I need to get several other pages in for 37 cents. How about a half page on light weight stock that has minimal advertising material and one photo that I could use in my mass mailings. I would keep the other brochure for giving out to people in my shop and people attending classes.

12. Any other comments or suggestions?

I could use more brochures any time. Lactation Assistance Services
Ruth Sweet, IBCLC
608-845-7269



# LACTATION CONSULTANT BERGENFIELD, N.).

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Date: Tue, 10 Feb 2004 09:24:02 -0500

From: WWOpal@aol.com 👸 Add to Address Book

To: gaapaa@yahoo.com

Subject: Re: The Boston Billow nursing pillow

This is such a great idea!

In a message dated 2/8/2004 11:14:55 AM Eastern Standard Time, gaapaa@yahoo.com writes:

> Dear Opal,

> I really want to personalize this - at least a little bit. Hope you arewell and we'll talk with you soon. Erik.

> Now, at the start of a new year, we contact our customers to get feedback about our Boston Billow nursing pillow, (the Billowpillow,) its quality and features as well as your view of our service and promotional materials. It is important that we hear from you so we can know where we stand and where we should focus our attention. Please therefore reply to the few questions listed below and return it to us. Thank you.

> What is your overall opinion of the Billowpillow?

I like it a lot and it's the only pillow I recommend.

> Do you find the Billowpillow suitably firm for its purpose? Usually it's a little too firm.

> Any comments about colors or patterns?

yes....my moms tend to prefer something less "busy" I may start just ordering the chambray unless you have a more subtle print that is unisex. Some of the sling fabrics are so nice, because they are prints that hide stains, for instance a navy with rows of tiny red hearts or pin dots. Do you know what I mean by "sling" fabrics? The sling is a baby carrier.

> We supply the Billowpillow with a wipeable cover for lactation consultants only, to be used for demonstration purposes, in NICUs etc.? Do you have them?

I have one.

> Some mothers have asked that we offer the Billowpillow with a waterproof cover for the inner pillow, while keeping the outer 100 percent cotton cover. This would make it considerably easier to keep the pillow

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From: "Jennifer and Fred Sienko" < sienko@empire.net > | Block Address | Add to Address

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Organization: 19 Paws North

To:gaapaa@yahoo.com Subject:Boston Billows

I just wanted to let you know how much I love my Boston Billow Nursing Pillow.

When I had my son in July of 2001 I had a little trouble nursing him at first. I couldn't find the "right" position. The lactation consultant at Concord Hospital brought in a Boston Billow and it truly made all

difference. Thanks to her suggestion I bought it on the spot and I am so glad that I did because I don't know if I would still be nursing without it. As I had a C-Section, the Billow made it extremely comfortable for me as well. I am still nursing my son and that Billow goes everywhere with us. It is a far superior product than a "Boppy".

Thank you! Jennifer Sienko Northwood, NH

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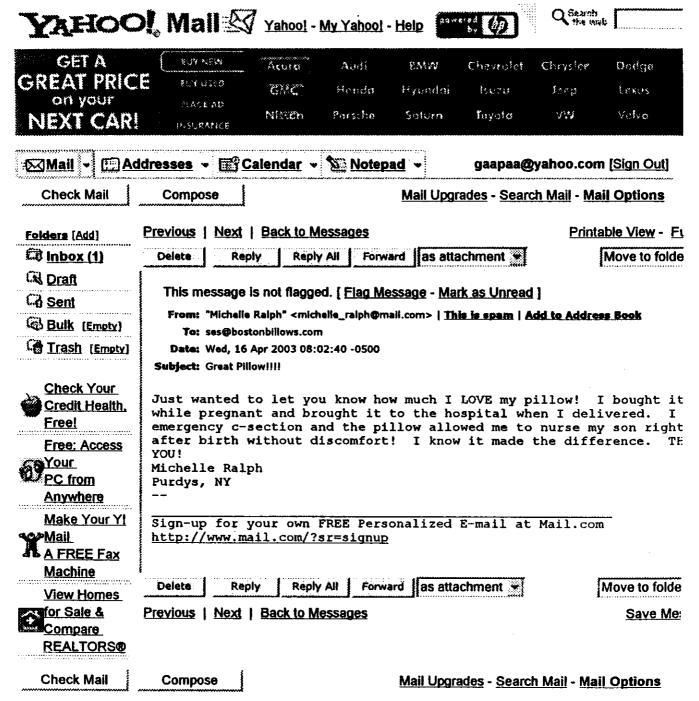
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